SUPPORT FOR THE AMENDMENTS

The present amendment cancels claim 55, and amends claims 21, 54 and 56.

Support for the amendment to claims 21, 54 and 56 is found at specification page 5, lines 7-12, and Figures 1 and 2.

It is believed that these amendments have not resulted in the introduction of new matter.

REMARKS

Claims 21-31, 54 and 56 are currently pending in the present application. Claim 55 has been cancelled, and claims 21, 54 and 56 have been amended, by the present amendment.

The rejection of claims 5-31 under 35 U.S.C. § 103(a) as being obvious over either Izumi (JP 11-060592) or Shin (JP 00-191685) in view of Endo is obviated by amendment with respect to claims 21-31, 54 and 56, and the previous cancellation of claims 5-20.

Amended claim 21 recites, in part, a liposomal composition comprising a cholestanyl glycoside according to formula (1), which has a sugar moiety selected from the group consisting of GlcNAcβ1,4Gal- and Fucα1,3Gal-, and exhibits antitumor activity, and a phospholipid and a positive-charge-providing substance capable of forming a liposome.

Izumi describes an anticancer medicine comprising a cholestanyl glycoside having a Fuc-Gal- sugar moiety (See e.g., abstract). Unlike the claimed invention, Izumi fails to disclose or suggest incorporating a cholestanyl Fucα1,3Gal- glycoside into a liposomal composition, which further comprises a phospholipid and a positive-charge-providing substance.

Shin describes an anticancer agent comprising a cholestanyl glycoside having a GlcNAc-Gal- sugar moiety (See e.g., abstract). Unlike the claimed invention, Shin fails to disclose or suggest incorporating a cholestanyl GlcNAcβ1,4Gal- glycoside into a liposomal composition, which further comprises a phospholipid and a positive-charge-providing substance.

Endo describes incorporating various hydrophilic or lipophilic active agents, including carcinostatic agents, into a liposomal composition comprising a phospholipid (e.g., dipalmitoylphosphatidylcholine) and a positive-charge-providing substance (e.g., an aliphatic amine, such as stearylamine) for the purpose of controlled and targeted release of the active agents, as well as the stabilization of unstable active agents (See e.g., column 1, lines 20-24,

column 2, lines 37-40 and 49-50, column 3, lines 57-59 and 64-65, and column 4, lines 51-52). The carcinostatic agents described in Endo include antitumor antibiotics (i.e., mitomycin, doxorubicin or adriamycin), antimetabolites (i.e., methotrexate and tegafur), a platinum compound (i.e., cisplatin), and a vinca alkaloid (i.e., vincristine) (See e.g., column 4, lines 51-52).

Endo fails to provide sufficient motivation and guidance to direct a skilled artisan to particularly select the claimed cholestanyl Fucα1,3Gal- glycoside anticancer agent and the claimed cholestanyl GlcNAcβ1,4Gal- glycoside anticancer agent from either the tremendously broad genus of hydrophilic or lipophilic active agents, or the preferred carcinostatic agents, described therein.

Even if sufficient motivation and guidance is considered to have been provided by Endo to direct a skilled artisan to particularly select the claimed cholestanyl Fucα1,3Gal-glycoside anticancer agent from the cholestanyl Fuc-Gal- glycoside of Izumi and/or the claimed cholestanyl GlcNAcβ1,4Gal- glycoside anticancer agent from the cholestanyl GlcNAc-Gal- glycoside of Shin for incorporation into the liposomal composition of Endo, such a case of obviousness is rebutted by a showing of unexpected results, as evidenced by the comparative experimental data presented in Figures 1 and 2 of the present specification.

Applicants have surprisingly discovered that the claimed liposomal composition comprising the cholestanyl glycoside according to formula (1), which has a sugar moiety selected from the group consisting of GlcNAcβ1,4Gal- and Fucα1,3Gal-, unexpectedly exhibits a remarkable degree of enhanced anti-tumor efficacy.

A general increase in antitumor efficacy attributable to incorporating cholestanyl anticancer agents into a liposomal composition may be reasonably expected, due to the stabilization and controlled/targeted delivery thereof (See e.g., the comparative experimental data of "Chol" and "Chol-Lipo" illustrated in Figures 1 and 2).

However, the presently claimed cholestanyl GlcNAcβ1,4Gal- glycoside and cholestanyl Fucα1,3Gal- glycoside anticancer agents *surprisingly exhibit a drastically enhanced antitumor efficacy far beyond that which may be reasonably expected* by the incorporation thereof into a liposomal composition (See e.g., the comparative experimental data of: "GlcNAcβ1,4GalChol" and "GlcNAcβ1,4GalChol-Lipo" illustrated in Figure 1; and "Fucα1,3GalChol" and "Fucα1,3GalChol-Lipo" illustrated in Figure 2).

Therefore, while a skilled artisan may have reasonably expected an enhancement in antitumor efficacy by incorporating the presently claimed cholestanol glycoside anticancer agents into the liposomal composition of the present invention, due to the stabilization and controlled/targeted delivery thereof, the *remarkable degree of enhanced anti-tumor efficacy actually exhibited by the liposomal composition of the present invention was quite unexpected.*

The evidence presented in Figures 1 and 2 of the present specification clearly illustrates that the presently claimed liposomal composition *unexpectedly exhibits a drastically enhanced antitumor efficacy.*

Withdrawal of this ground of rejection is respectfully requested.

In conclusion, Applicants submit that the present application is now in condition for allowance and notification to this effect is earnestly solicited.

Respectfully submitted,

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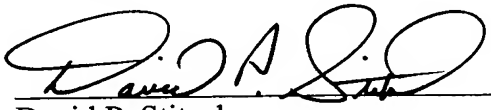

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